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Abstract: This single-centre, prospective trial was designed to assess the efficacy of a new retrograde transillumination device called the 'Infrared Red Intubation System' (IRRIS) to aid videolaryngoscopic tracheal intubation. We included 40 adult patients, who were undergoing elective urological surgery under general anaesthesia. We assessed the ability to differentiate the transilluminated glottis from other structures and found a median (IQR [range]) larynx recognition time of 8 (5–14 [3–28]) s. The difference in laryngeal visibility on the screen between the deactivated vs. activated device expressed on a visual analogue scale was significant (6 (4–7 [2–10]) vs. 10 (8–10 [4–10]); $p < 0.001$). The number of laryngoscope insertions was 1 (1–2 [1–3]) and the device showed high values on a visual analogue scale ranging from 0 (lowest score) to 10 (highest score) for helpfulness (6 (5–7 [2–10])), credibility (10 (8–10 [5–10])) and ease of use (10 (9–10 [8–10])). Tracheal intubation with the system lasted 26 (16–32 [6–89]) s. No alternative technique of securing the airway was necessary. The lowest SpO2 during intubation was 98 (97–99 [91–100])%. We conclude that this method of retrograde transillumination can assist videolaryngoscopy.

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A new retrograde transillumination technique for videolaryngoscopic tracheal intubation

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Short title: Retrograde transillumination for video-laryngoscopy

Keywords
Airway management: difficult intubation, video-laryngoscopy, retrograde transillumination

Summary

This single-centre, prospective trial was designed to assess the efficacy of a new retrograde transillumination by the "Infrared red intubation system" (IRRIS) to aid videolaryngoscopic tracheal intubation. We included 40 adult patients, who were undergoing elective urological surgery under general anaesthesia. We assessed the ability to differentiate the highlighted glottis from other structures and found a median (IQR [range]) larynx recognition time of 8 (5-14 [3-28]) sec. The difference in laryngeal visibility on the screen between the deactivated vs. activated device expressed on a visual analogue scale was significant (6 (4-7 [2-10]) vs. 10 (8-10[4-10]) sec; $p < 0.001$). The number of laryngoscope insertions was 1 (1-2 [1-3]) and the device showed high values on a visual analog scale ranging from 0 (lowest score) to 10 (highest score) for helpfulness (6 (5-7 [2-10])), credibility (10 (8-10 [5-10])), and ease of use (10 (9-10 [8-10])). Tracheal intubation with the system lasted 26 (16-32 [6-89]) sec. No alternative technique of securing the airway was necessary. The lowest SpO_2 during intubation was 98 (97-99 [91-100])%, We conclude that this method of retrograde transillumination can assist videolaryngoscopy.

Introduction

Videolaryngoscopy is now established in routine anaesthesia practice and recommended as a first or second line alternative technique in the case of expected difficult airway situations [1-4]. However, videolaryngoscopy has certain limitations, in particular in the hands of less experienced users [5,6]. Several adjuncts and maneuvers are suggested to improve performance including using a flexible, rigid or malleable stylet within the tracheal tube to facilitate intubation [7], or using transillumination (such as with the Trachlight™, Saturn Biomedical System Burnaby, BC, Canada, or the Search-Lite™, Bovie Medical Corporation, Clearwater, FL, USA) [8 -11]. One important limitation is that these latter methods require the device itself to intubate the trachea and the light is viewed emitted from within the lumen externally on the skin. An alternative approach is the transillumination of light in the opposite direction, from the skin and viewed from within the tracheal lumen ('retrograde' illumination) [12].

The "Infrared Red Intubation System" (IRRIS) technique is a recent revival of retrograde transillumination, albeit in a fundamentally different way. Instead of visible light, it emits infrared/near-infrared light into the tissue, which in turn is visualized by the camera of a video-endoscope, thus resembling a beacon from within the airway so that one can see a blinking light inside the trachea and the glottis [13]. This has the potential to discriminate between the glottis and its surroundings, by causing a stronger contrast between the glottis and the neighboring structures. The purpose of this was to assess the impact on the performance of videolaryngoscopy using this method.

Materials and Methods

The disposable IRRIS device (Guide In Medical, Nazareth, Israel) is CE marked: the size of a matchbox, it is attached to the anterior skin of the neck cranial to the sternal notch and caudal to the thyroid cartilage, preferably on the skin covering the cricothyroid membrane [13]. It is fixed on the neck skin with adhesive stripes on both of its sides (Figure 1). For the duration of 10 min after activation, IRRIS emits a specific infrared/near infrared light at a wavelength between 730 - 1000 nm in a waxing and waning intensity, which penetrates the adjacent tissues of the anterior neck region. The emitted

light is invisible to the naked eye, but video systems translate it to visible light on their monitor screen (Figure 2). The novelty of IRRIS is that it exclusively highlights the glottic opening while all other structures remain dark, thus distinguishing it from other transilluminating devices based on visible light. Since the emitted light is invisible for the eye, IRRIS does not work with direct laryngoscopy. Videolaryngoscopes and flexible endoscopes that have no infrared filter allow the IRRIS signal to be seen on their screen, as a shining light from the glottis. In these endoscopes, the image on the screen shows the larynx with a bright white light shining like a beacon from within the trachea towards the observer. The main purpose of this feature is to distinguish the airway from the esophagus as well as from adjacent structures or mucosal folds that could represent a 'false passage' for the advancement of the tracheal tube. After successful intubation, the IRRIS device is removed from the neck and discarded.

After approval from the local Ethics Committee, 40 consecutive patients of both genders, for elective urological surgery requiring general anaesthesia and orotracheal intubation were included. Further inclusion criteria were age > 18 years, all Mallampati scores 1 - 4, ASA physical status 1 to 3. We excluded emergency cases and pregnant women.

One operator, experienced with videolaryngoscopy conducted the study (PB). Laryngoscopy was performed by the same anaesthesiologist (PB) by using a KingVision™ video-aryngoscope (Ambu A/S, Baltorpbakken 13, 2750 Ballerup, Denmark) with disposable channeled and unchanneled blades [2,6]. When using unchanneled blades the tracheal tubes were armed with a malleable guidewire (Shiley™, Covidien™, 15 Hampshire Street, Ireland), which was shaped to a curved and a terminally hockey-stick resembling form [14].

Before inducing anaesthesia, an activated IRRIS device was adhered to the anterior skin of the neck above the sternal notch. After confirming lack of discomfort, anaesthesia was induced by using fentanyl 5 µg.kg-1, propofol 2 mg.kg-1, and rocuronium 0.8 mg.kg-1. The following parameters were observed and documented by the intubating person:

(a) visible distinction of illuminated laryngeal structure from non-illuminated neighboring structures and in particular from the esophagus (yes or no)
(b) visibility of the glottic entrance during both, the phase when the light source was ON and when the light source was OFF (according to a subjective visual analog scale "VAS" from 0 (very poorly visible) to 10 (very well visible)
(c) time to recognize the illuminated laryngeal inlet after insertion of the video-laryngoscope (s)
(d) subjective degree of helpfulness of the visual aid by the device according a Visual Analog Scale (VAS from 1 = not helpful at all to 10 = very helpful)
(e) subjective degree of credibility of IRRIS to recognize the correct intubation pathway according a a Visual Analog Scale (VAS from 1 = not credible at all to 10 = very credible)
(f) subjective degree of easiness of IRRIS handling on a Visual Analog Scale (VAS from 1 = very difficult to 10 = very easy)

Intubation performance was considered to be indirectly influenced by the impact of the retrograde transillumination. To assess intubation performance, we documented the following parameters:

(a) success of videolaryngoscopic tracheal intubation within 30 sec (yes or no)
(b) time to conclude intubation from inserting the videolaryngoscope until the tracheal tube cuff was inflated (s)

(c) subjective degree of difficulty of intubation according a Visual Analog Scale (VAS from 1 = very easy to 10 = extremely difficult)
(d) in case of intubation failure: necessity of alternative airway securing method or abort of tracheal intubation if initial attempt(s) with IRRIS failed (number and choice of alternative techniques)

After successful tracheal intubation, the IRRIS device was removed and discarded. Maintenance and emergence of anaesthesia (either with sevoflurane or propofol infusion and neuromuscular blockade) was conducted according to the local standards and the individual needs of patient and surgery. Postoperative checks of the neck skin condition were performed at 3 time periods after removal of the IRRIS device: immediately after removal, after 2 h and after 24 h.

Statistical analyses were performed using Microsoft Excel for Mac (Microsoft, Redmond, WA, USA) and GraphPad Prism for Mac Version 6.0 (GraphPad Inc., La Jolla, CA, USA). Normally distributed data are shown as mean (standard deviation), not normally distributed data are presented as median (interquartile range [range]). Comparisons were made using the Wilcoxon matched-pairs signed rank test.

Results

The patient characteristics are shown in Table 1. All tracheal intubations were successfully accomplished with the initial video-laryngoscopic and retrograde transilluminated IRRIS-guided technique, and in no patient an alternative technique was needed.

IRRIS was successful and without side-effects in all 40 patients. No patient described any discomfort when awake. Retrograde transillumination by IRRIS highlighted the laryngeal inlet on the screen of the KingVision™ clearly in all 40 patients, while all other structures – and in particular the oesophagus - remained much darker (Figures 1 and 2). The difference in laryngeal visibility on the screen between activated vs. deactivated IRRIS device expressed on the VAS was significant (off vs. on 6 (4-7 [2-10]) vs. 10 (8-10[4-10]); $p < 0.001$). The details of IRRIS's performance in distinctly illuminating the larynx are summarized in Table 2. In the most obese patient in our cohort (with a BMI of 46.2 and a neck circumference of 56 cm), the vocal cords were not visible without IRRIS because the supraglottic tissue appeared to be very abundant. Its appearance caused the glottis to be unrecognizable. In this specific case, the IRRIS clearly indicated the right pathway.

Tracheal intubation was successfully performed in all patients using the initially intended technique. There was a broad difference in both the objectively measured parameters (such as intubation duration and resulting lowest SpO_2 during the airway manipulations), as well as in the subjective categorization concerning its difficulty level (Table 3). No patient complained about discomfort during the awake period prior anaesthesia induction, while the IRRIS device was already place on the anterior neck surface. The examination of the affected skin at all 3 time intervals (immediately after removal, 2 hours and 24 h later) revealed no change in colour or integrity.

Discussion

We have confirmed the ability of IRRIS to highlight the glottis on the screen of a videolaryngoscope in a way that appears to assist tracheal intubation. This is the case even in obese patients in our cohort.

The time to recognize the illuminated larynx after passing the dental row with the blade of the video-laryngoscope was 8 (5-14 [3-28]) sec, including one particularly difficult case. In this specific case, more time was necessary to advance the video-laryngoscope into the best possible position due to a limited mouth opening and a large tongue base. As soon as the epiglottis could be lifted, the illuminated laryngeal inlet became clearly visible on the screen.

Anterograde light guided intubation with the aid of an illuminated stylet has been employed in the past with mixed results [9,14]. Only one group reported the use of a retrograde transillumination technique [12], but they applied visible light, which does not specifically highlight the airway. Commercially available anterograde transillumination devices such as the TrachlightTM and Surch-LiteTM stylets can be viewed as predecessors of IRRIS, but they have crucial limitations: they require suitably dimmed ambient light conditions (which are not always present) and are strongly dependent on the tissue thickness of the anterior neck region [8,9,11]. To send visible light from the anterior surface of the neck in a reverse direction to the larynx, and to view it during direct laryngoscopy seems to be at first glance a compelling alternative; however, this is technically not possible because visible wavelengths are not suitable to penetrate and selectively illuminate the airway. Conversely, infrared/near-infrared light shows a superior penetrance to hollow organs such as the trachea. This causes the desired effect of explicitly highlighting the glottis, if visualized with a suitable video-endoscope [13]. The latter has to translate the “invisible” infrared light to visible light on the video screen of the device. This is the reason, why IRRIS works exclusively with video-laryngoscopes, flexible and rigid video-endoscopes that have no inbuilt infrared filter and similar devices only. The manufacturer informed us, that several video-endoscopic devices display the light from IRRIS on their screens, and those which do not have this feature, may be modified accordingly. Prior to application of the IRRIS technique, the user has to make sure, that the video-endoscopic device to be employed has this necessary capability.

The parameters dealing with the IRRIS performance were distinctly positive: besides the mentioned short larynx recognition time, we needed only one insertion to successful viewing in 31 of 40 cases (77.5%), 2 attempts in 6 cases (15%) and 3 in 1 case (7.5%). In accordance with other authors, we also emphasize the importance of first pass success in tracheal intubation as a major determinant of method quality and suitability [15]. We obtained high scores for the subjective image quality and usefulness assessments. It has to be emphasized in this context, that the obtained performance results derived from one, experienced user. We chose this “best user” study design to exclude the personal skill as a confounder in this first clinical investigation of IRRIS that focuses on obtaining baseline values in this initial study. Nevertheless, the individual skills of the specific user in recognizing the anatomy are relevant and it will important to assess if novices find the method useful.

We conclude that the disposable Infrared/Red Intubation System “IRRIS” is suitable for retrograde transillummination of the larynx, when it is viewed via a suitable video-laryngoscope and provides a clear highlighting of the intubation pathway as compared with the adjacent structures, including the oesophagus. IRRIS improves the differentiability of the intubation pathway by selectively highlighting the relevant structures. There was no discomfort or harm to any of the patients, whose

video-laryngoscopic intubation was facilitated by the use of this new retrograde transillumination device.

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Conflicts of Interest: PB has received travel allowances by Merck Sharp & Dohme and by Acutronic Medical Systems. He is Medical Advisor of GuideIn Medical. EF is one of the inventors and developers of the IRRIS device, and is holder of the patent. He is a co-founder and medical consultant of GuideIn Medical. MS has received travel support from Baxter, Switzerland in the past. MSK is an unpaid member of the Scientific Advisory Board for Ambu (Ambu A/S, Baltorpbakken 13, 2750 Ballerup, Denmark).

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Table 1. Patient characteristics. Values are mean (SD), median (IQR [range]) or distribution of n.

Height; cm	Weight; kg	Age; years	Body mass index BMI; $kg.m^{-2}$	Neck circumference; cm	Gender distribution M:F; n	Mallampati grades distribution (n; 1/2/3/4)	ASA class distribution (n; 1/2/3)
176 (7)	80 (76-94 [55-140])	66 (59-73 [27-89])	26 (24-27 [20-46])	42 (5)	34:6	18/17/3/2	8/25/7

Table 2. Performance of video-laryngoscopy with retrograde transillumination in all 40 patients (descriptive statistics; n or median (IQR [range]). VAS = visual analog scale *(VAS 0 = low; 10 high; $p < 0.001$ vs. ON); **(VAS 0 = low; 10 high; $p < 0.001$ vs. OFF)

Visible distinction of illuminated laryngeal (yes/no)	40 / 0
Time to see larynx visible on screen from turning on IRRIS (s)	8 (5-14 [3-28])
Number of insertion attempts of the video-laryngoscope (n)	1 (1-2 [1-3])
Level of device helpfulness to recognize the larynx*	6 (5-7 [2-10])
Level of device credibility for its purpose*	10 (8-10 [5-10])
Level of device ease of use for its purpose*	10 (9-10 [8-10])
Larynx visibility with the device OFF*	6 (4-7 [2-10])
Larynx visibility with the device ON**	10 (8-10[4-10])

Table 3. Intubation performance using IRRIS (descriptive statistics; n or median (IQR [range]); *VAS 0 = low; 10 high.

Intubation accomplished with initial technique (yes/no)	Yes 40 / No 0
Intubation success in 1st attempt and under 30 s (yes/no)	Yes 31 / No 9
Number of intubation attempts (n = 1/2/3)	31/ 6/ 3
Time till successful intubation (s)	26 (16-32 [6-89])
Level of intubation difficulty*	5 (3-7 [1-9])
Lowest pulse oximetric oxygen saturation during intubation (%)	98 (97-99 [91-100])

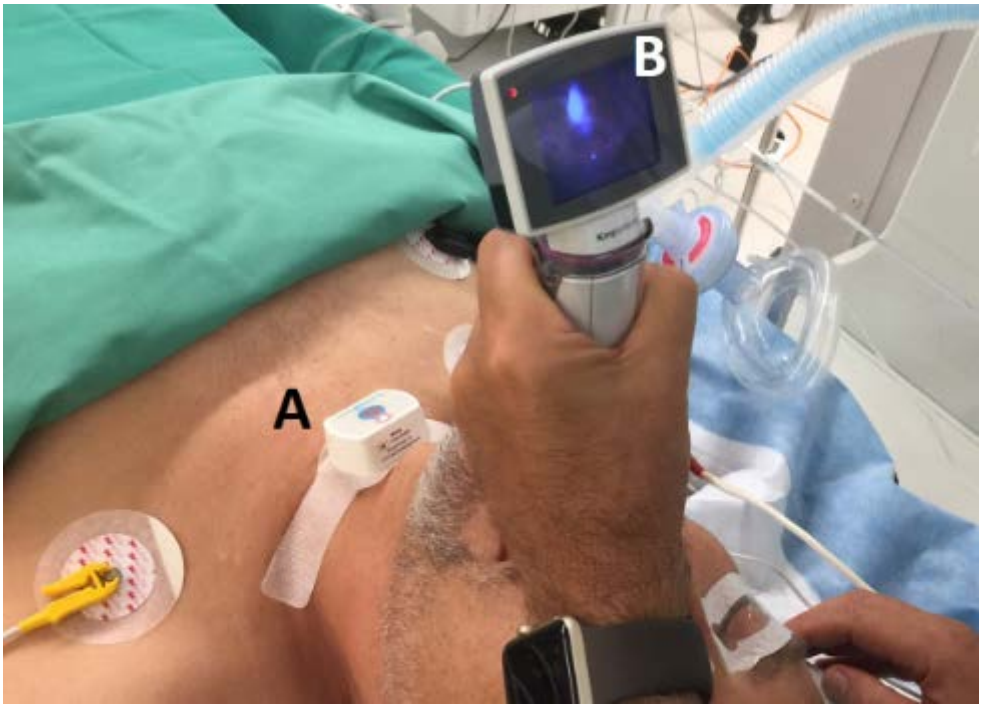

Figure 1. Activated IRRIS device (A) in place during video-laryngoscopy with a KingVision™ laryngoscope. The glottis is highlighted by a distinctive shining on the video screen (B).

Figure 2. The difference in video-laryngoscopic monitor view with an inactive (left) and activated (right) IRRIS device.